

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0129]

DMB

Display Date	6-27-01
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Certifier	REEP

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Implementation of the Biomaterials Access Assurance Act of 1998

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Implementation of the Biomaterials Access Assurance Act of 1998

The Biomaterials Access Assurance Act of 1998 (BAA98) (21 U.S.C. 1601-1606) establishes a mechanism to protect biomaterial suppliers of implanted medical devices from liability in civil

actions. BAA98 includes exceptions for when protection from liability is not available to suppliers. One of those exceptions is when a supplier acts as a manufacturer of the implanted device. BAA98 says that a biomaterials supplier may be considered a manufacturer of a medical device if the supplier is the subject of an FDA declaration that the supplier was required to register under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and failed to do so, or was required to list its device under section 520(j) of the act (21 U.S.C. 360(j)) and failed to do so.

BAA98 allows persons to petition FDA for a declaration that a biomaterials supplier should have registered its establishment or listed its device with FDA, and failed to do so. Petitioners are requested to include information about the prerequisites for filing a petition. This information includes the following: (1) A civil suit has been filed in State or Federal court alleging that an implant directly or indirectly caused harm; (2) the suit was filed after August 13, 1998; and (3) the manufacturer of the implant was named as a party to the civil action. Petitioners are also requested to include information to identify the following: (1) The final product and how it is intended to be used, (2) the activities the supplier performs on the device, and (3) the name as well as type of entity or person to which the supplier sends the device. These draft reporting requirements are intended to provide FDA with sufficient information to show that the prerequisites for filing the petition are met and determine whether a biomaterial supplier should have registered its establishment or listed its device with FDA, and failed to do so.

In the **Federal Register** of April 2, 2001 (66 FR 17562), the agency requested comments on the proposed collection of information. No comments were received.

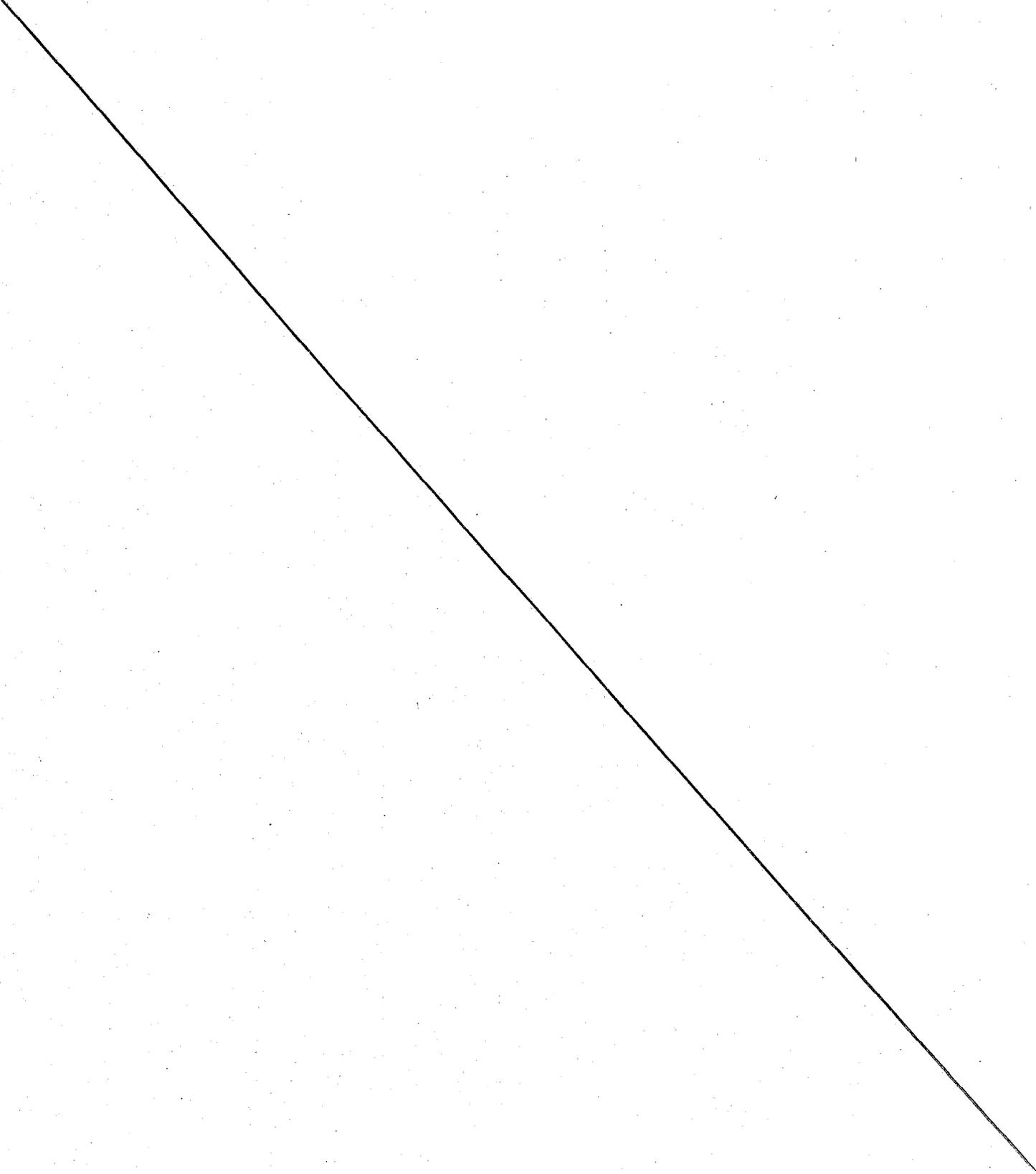
FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
5	1	5	1	5

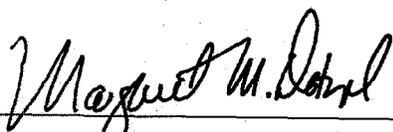
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

BAA98 became effective August 13, 1998. Up until the current date, no petitions for declaration have been filed with FDA. However, FDA believes that in future years a handful (estimated at 5) of petitioners may file with the agency. FDA estimates that respondents would



take approximately 1 hour to gather the requisite information and draft a petition. The likely respondents to this collection of information are persons involved in civil actions based on harm arising from an implanted medical device.

Dated: 6/18/01
June 18, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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